

## **REMARKS**

### **I. Status of the Claims**

Claims 1-40 were originally filed. Subsequently, claims 1-40 have been canceled and claims 41-48 have been added. Upon entry of the present amendment, claim 41 is amended to recite that the polypeptide encoded by the claimed nucleic acid comprises an amino acid sequence at least 90% identical to SEQ ID NO:5. Claim 42 is amended to recite an at least 95% sequence identity. The amendment to these two claims is supported by the specification, *e.g.*, on page 11, line 28, to page 12, line 5. Claim 43 is amended to recited that the claimed nucleic acid encodes a polypeptide comprising either SEQ ID NO:4 or SEQ ID NO:5, which is generally supported by the specification. No new matter is added by this amendment.

### **II. Claim Rejections**

#### **A. 35 U.S.C. §112, First Paragraph: Enablement**

In the Final Office Action mailed August 25, 2003, the Examiner sustained the enablement rejection of claims 41-48 under 35 U.S.C. §112, first paragraph. Applicants respectfully traverse the rejection.

In raising the enablement rejection, the Examiner indicated that the specification is enabling for a nucleic acid encoding the amino acid sequence of SEQ ID NO:4 or 5, but is not enabling for the claim scope defined by the hybridization language. The Examiner's concerns appeared to reside in the purported lack of predictability of protein functions based on sequence homology (pages 4-6 of the Office Action mailed March 12, 2003).

The enablement analysis requires the consideration of several factors: the breadth of the claims; the nature of the invention; the state of the prior art; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the contents of the disclosure. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). As discussed in Applicants' response filed June 4, 2003, the present invention is one within the field of molecular biology and electrophysiology, where the relevant knowledge is abundant and technical skill is high. In

addition, the present application also provides ample guidance for one of skill in the art to make and use the claimed invention. Moreover, the experimentation of generating sequence variants of a reference polypeptide and testing their functionality as a voltage-gated KCNQ potassium channel relies on routine techniques and is the kind that the art typically engages in. In light of these considerations, Applicants contend that the present claim amendment has reasonably addressed the Examiner's specific concerns regarding enablement.

As amended, the pending claims are directed to an isolated nucleic acid encoding a polypeptide, which comprises an alpha subunit of a KCNQ potassium channel, wherein said polypeptide forms, with at least one additional KCNQ alpha subunit, a KCNQ potassium channel having the characteristic of voltage-gating, and comprises an amino acid sequence that is at least 90% identical to SEQ ID NO:5. Thus, the amended claim language more clearly defines the claim scope in that no more than 10% of all amino acid residues of the core sequence may be altered from a reference sequence, *i.e.*, SEQ ID NO:5. Furthermore, the specification provides several amino acid sequence alignment results among related KCNQ channel subunits, *e.g.*, Figures 1 and 2, which tend to lend suggestions to a skilled artisan which particular residues within SEQ ID NO:5 are likely to tolerate modification without loss of functions. Similar sequence alignment could also be accomplished by the artisan since other KCNQ family members were known at the time this application was filed. Thus, the quantity of necessary experimentation is limited.

For these reasons, Applicants submit that the specification is sufficiently enabling for the amended claims. As such, the withdrawal of the enablement rejection is respectfully requested.

**B. 35 U.S.C. §112, First Paragraph: Written Description**

The Examiner also sustained the written description rejection of claims 41-48 under 35 U.S.C. §112, first paragraph. Specifically, the Examiner argued that the disclosure does not provide enough description for a skilled artisan to envision the infinite number of polynucleotide sequences encompassed by the claims, which, when defined by the hybridization

language, cover numerous structural variants. Applicants contend that the present amendment allows a better definition of the claimed invention and enables the specification to meet the written description requirement.

As discussed in Applicants' response filed June 4, 2003, the written description requirement can be satisfied by providing commonly shared structural and functional characteristics of the claimed genus of nucleic acids. As amended, the pending claims are directed to a genus of nucleic acids that share one common structural feature: they encode polypeptides comprising a core sequence that is at least 90% identical to SEQ ID NO:5. Common functional feature is also provided: the polypeptides can participate in forming a voltage-gated KCNQ potassium channel.

Apparently focusing on the structural aspect of how the claimed nucleic acids are described, the Examiner repeatedly asserted that insufficient description has been provided to allow a skilled artisan to envision the detailed structure of the infinite number of nucleic acids covered by the claims (page 8 of the Office Action of March 12, 2003, and page 8 of the Final Office Action of August 25, 2003). In light of the present claim amendment, Applicants contend that the specification does provide a sufficiently detailed description of the claimed genus of nucleic acids, which would allow one ordinarily skilled artisan to envision variants of the genus. First of all, the present amendment allows a more clear structural definition of the claimed nucleic acids by more specifically defining the amino acid sequences encoded by the nucleic acids, namely, a variant nucleic acid within the claim scope must encode a polypeptide containing a core sequence no more than 10% different from SEQ ID NO:5. Secondly, given the level of general knowledge and technical skill in the relevant field, and particularly the knowledge of other KCNQ family members, a person of skill in the art would be able to, with reasonable ease, generate variants of SEQ ID NO:1, 2, or 3 and verify the desired function of polypeptides they encode: *i.e.*, the capability of forming a voltage-gated KCNQ potassium channel. The specification thus does reasonably convey to an artisan that the inventors indeed had in their possession at the time this application was filed the invention as defined by the amended claims.

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As such, Applicants believe that the written description requirement is met and hence respectfully request the withdrawal of this rejection.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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